MAR - 3 2004

8.0 510(k) Summary

SUBMITTER:	B. Braun Medical Inc. 901 Marcon Boulevard Allentown, PA 18109-9341 (610) 266-0500, ext. 2280 Contact: Patricia D. Wilson, Regulatory Affairs Specialist
DEVICE NAME:	B. Braun Premixed Dialysate
COMMON OR USUAL NAME:	Premixed Dialysate
DEVICE CLASSIFICATION:	Class II, 21 CFR § 876.5820, Hemodialysis System and Accessories (Product Code KPO)
PREDICATE DEVICE:	NxStage Medical, Inc. - NxStage Premixed Dialysate (K022913) Gambro Renal Products – Gambro PrismaSate Dialysis Solutions for Continuous Renal Replacement Therapy (K013448) Baxter Healthcare Corporation –Baxter Premixed Dialysate for Hemodiafiltration (K910270)
DESCRIPTION:	The B. Braun Premixed Dialysate Solutions are a family of premixed dialysate solutions which are sterile, non-pyrogenic solutions to be provided in single use flexible PVC bags varying in sizes from 1000 mL to 5000 mL. The premixed dialysate solutions are intended for use with renal replacement therapy systems that utilize sterile premixed dialysate. A family of dialysate solutions will allow the physician to prescribe different electrolyte compositions that meet the specific needs of individual patients.
INTENDED USE:	B. Braun Premixed Dialysate is indicated for use with renal replacement therapy systems that utilize sterile premixed dialysate.
SUBSTANTIAL EQUIVALENCE:	B. Braun believes that, within the meaning of the Medical Device Amendments of 1976, the B. Braun Premixed Dialysate addressed in this 510(k) premarket notification is substantially equivalent to the following medical devices in commercial distribution:

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SUBSTANTIAL EQUIVALENCE (continued):

- NxStage Premixed Dialysate (K022913, cleared 10/21/02)
- PrismaSate Dialysis Solutions (K013448, cleared 01/15/02)
- Baxter Premixed Dialysate for Hemodiafiltration (K910270, cleared 04/18/91)

The B. Braun Premixed Dialysate includes the same chemical composition range, and has the same manufacturing, packaging, and sterilization process as the NxStage Premixed Dialysate (K022913). The B. Braun Premixed Dialysate is also similar to the Gambro PrismaSate Solutions (K013448), and Baxter Premixed Dialysate (K910270), with regard to composition, sterility, and packaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2004

Ms. Patricia Wilson
Regulatory Affairs Specialist
B. Braun Medical, Inc.
901 Marcon Boulevard
ALLENTOWN PA 18109

Re: K034066
Trade/Device Name: B. Braun Premixed Dialysate
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: December 30, 2003
Received: December 31, 2003

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K034066

Device Name: **B. Braun Premixed Dialysate**

Indications For Use:

B. Braun Premixed Dialysate is indicated for use with renal replacement therapy systems that utilize sterile premixed dialysate.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K034066